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PATENT APPLICATION FOR

MULTIPOLEAR ELECTRODE SYSTEM FOR VOLUMETRIC RADIOFREQUENCY
ABLATION

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ABLATION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of provisional application Serial No. 60/315,383 filed August 28, 2001, entitled “A Device to Allow Simultaneous Multiple Probe Use During Application of Radio Therapy”; hereby incorporated by reference, a continuation-in-part of U.S. Application 09/873,541 filed June 4, 2001 claiming the benefit of provisional application Serial No. 60/210,103 filed June 7, 2000 entitled “Multipolar Electrode System for Radio-frequency Ablation”; and further a continuation of U.S. Application 10/167,681 filed June 10, 2002 entitled “Radio-Frequency Ablation system Using Multiple Electrodes”.

STATEMENT REGARDING FEDERALLY
SPONSORED RESEARCH OR DEVELOPMENT

[0002] Not applicable.

BACKGROUND OF THE INVENTION

[0003] The present invention relates to electrodes for radiofrequency ablation of tumors and the like, and in particular to a multipolar electrode system suitable for the ablation of volumetric liver tumors.

[0004] Ablation of tumors, such as liver (hepatic) tumors, uses heat or cold to kill tumor cells. In cryosurgical ablation, for example, cold is used to kill the tumor by inserting a probe during an open laparotomy and freezing the tumor. In radiofrequency ablation (RFA), on the other hand, an electrode is inserted into the tumor and current passing from the electrode into the patient (to an electrical return typically being a large area plate on the patient's skin) destroys the tumor cells through resistive heating. A major advantage of RFA, particularly in comparison to cryosurgical ablation, is that treatment may be delivered percutaneously, without an incision, and thus with less trauma to the patient. In some cases, RFA is the only treatment the patient can withstand. Further, RFA can be completed while the patient is undergoing a CAT scan.

[0005] Due to the advantages associated with RFA ablation, a number of RFA electrodes for providing tumor ablation procedures have been developed. In one prior art method, a conductive needle having an uninsulated tip is placed within the tumor, and the needle is

energized with respect to a large area contact plate on the patient's skin by an oscillating electrical signal of approximately 460 kHz. Current flowing radially from the tip of the needle produces a spherical or ellipsoidal zone of heating (depending on the length of the exposed needle tip) and ultimately a lesion within a portion of the zone having sufficient temperature to kill the tumor cells. While certain advantages are gained from using a single needle, particularly in limiting the invasiveness of the procedure, this "monopolar" method is limited in the size of the tumor which can be treated due to fall-off in current density away from the electrode, loss of heat to the surrounding tissue, and limits on the amount of energy transferred to the tissue from the electrode.

[0006] Because of the limited treatment size and other known limitations associated with monopolar RFA ablation, RFA ablation methods which provide current between two or more needles have also been developed. In these "bipolar" methods, two needles are provided on a shaft. In one known method, for example, the needles are spaced along the length of the shaft, and one needle is positioned, for example, on each side of a tumor. Current can then be passed either through each of the needles, with reference to a ground plane, as described above, or in bipolar mode with the two needles. In this way, the amount of tissue which can be treated at one time is increased. However, when using this method, the treatment area is substantially limited to the area defined between the two needles. To provide ablation for a volume, therefore, the shaft must be rotated, thereby increasing the invasiveness of the procedure and, due to the changing locations of the needles, limiting the ability to adequately monitor and control the heating process.

[0007] In a second known method, the two or more needles are extended outwardly from and parallel to an end of a shaft. Here, again, the needles can be provided on opposing sides of a tumor. As in the example above, the amount of tissue which can be treated at a single time is therefore increased as compared to monopolar operation, but the treatment is again limited to the area between the needles. A three dimensional volume of tissue, therefore, cannot be adequately treated unless the probe is rotated, or a third needle is added and treatment multiplexed among the three needles. Even when the treatment is multiplexed, however, treatment is limited to successive single dimensional planes between pairs of needles. Therefore, the treatment period is long, and the treatment is complicated and difficult to both monitor and control.

[0008] Because of these difficulties, known RFA methods often fail to kill all of the tumor cells in a selected volume and, as a result, tumor recurrence rates of as high as 40% have been reported.

SUMMARY OF THE INVENTION

[0009] The present inventors have developed a method for treating a tumor volume with improved efficiency while limiting the invasiveness of the treatment and improving treatment control. The method overcomes the limitations of current electrode designs by adopting a multipolar electrode that increases the treatable tumor size. Energy is focused on the tumor volume between two or more sets of electrodes, thereby simultaneously treating a larger volume of tissue than was possible in the prior art. By using axially displaced umbrella electrodes supported by outwardly non-conductive shafts, a large volume lesion area is created between two planes, and the entire volume between the planes is treatable simultaneously. This method therefore provides an improvement over prior art monopolar and bipolar treatment methods, both in decreasing treatment time, and simplifying control of the treatment.

[0010] Specifically, the present invention provides a method for ablating a volume of tissue in a patient in which a first plurality of electrode wires are radially extended at a first position adjacent the volume of tissue to radial points defining a first plane, and a second plurality of electrode wires are radially extended at a second opposing position adjacent the volume of tissue to radial points defining a second plane, and offset from the first plane. A power supply is connected between the first plurality and second plurality of electrode wires to induce a current flow between them through the tumor volume. Therefore, a volume of tissue provided between the first and second planes can be ablated simultaneously.

[0011] In another aspect of the invention, the first and second plurality of electrode wires are provided in umbrella electrode sets, each including at least three radially extending electrode wires.

[0012] In another aspect of the invention, the electrode wires of the first and second electrode sets are provided at radial points separated by substantially equivalent angles around a defined center point. The first and second electrode sets can, for example, be tripartite. Here, each of the wires in the tripartite electrode is offset from another of the wires in the tripartite electrode by substantially one hundred and twenty degrees. The electrode wires in each tripartite electrode set can also be aligned.

[0013] In another aspect of the invention the method includes monitoring a temperature level at each of the first and second pluralities of electrode wires. A voltage applied between the first and second sets of electrodes can also be controlled to maintain the temperature within a predetermined temperature range. Particularly, a temperature sensor can be provided at each

electrode wire in the electrode set, thereby allowing for monitoring the temperature of the tissue at a plurality of locations in the volume, and controlling the energy dispersion as a function of temperature throughout the volume. Additionally, the electrode wires in each electrode set can be isolated and controlled separately, thereby maintaining temperature control throughout the volume.

[0014] Thus, in one aspect of the invention, multi-electrode systems can be used to define arbitrary volumes and accurately control temperature within those volumes for complete tumor ablation. By maintaining individual control over the current flow through the electrodes provided in disparate portions of the tumor, adjustments can be made to account for inhomogeneities in the tissue such as, for example, nearby blood vessels which carry heat away from nearby tissue. By further using a conductive plate to augment current flow in one electrode, energy delivery at that electrode may be increased without changing the energy delivery at the other electrode, thereby providing the ability to vary the heat delivery significantly in various portions of the tumor.

[0015] The present invention also provides a method for ablation of a tumor volume in a patient comprising the steps of inserting a first electrode having a first support shaft and a first umbrella electrode set percutaneously at a tumor volume so that the first umbrella electrode set is at a first location adjacent to the tumor volume and offset from a center of the tumor volume, inserting a second electrode having a second support shaft and a second umbrella electrode set percutaneously at a tumor volume so that the second umbrella electrode set is at a second location opposed and at a predetermined separation from the first location and about the tumor volume, and extending the first and second umbrella electrodes sets radially from the first and second shafts to an extension radius wherein the electrode wires of the first umbrella electrode set are provided at radial points defining a first plane and the electrode wires of the second umbrella electrode are provided at radial points defining a second plane. A power supply is connected between the first and second electrode umbrella sets to induce a current flow between them through the tumor volume whereby current induced heating is concentrated in the tumor volume defined between the first and second plane.

[0016] In another aspect, the present invention provides an electrode assembly for ablating tumors in a patient. The electrode assembly includes a support shaft sized for percutaneous placement in the patient, first and second wire electrode sets extensible radially from the shaft to an extension radius, each wire of each wire electrode set being offset from the other wires in the wire electrode set at radial points defining a plane, and a power supply connected

between the first and second electrode sets to induce a current flow between the first and second electrode sets. The first wire electrode set is positionable adjacent to a tumor volume and offset from a center of the tumor volume and the second retractable electrode set is positionable at a second location opposed from the first location about the tumor volume such that the current flow is through the tumor volume.

[0017] In another aspect of the invention, each of the electrode sets in the electrode assembly can comprise a tripartite electrode, and at least one temperature sensor can be coupled to each of the first and second electrode sets. A controller can also be connected to the temperature sensor to receive temperature level signals from each of the first and second electrode sets and to the first and second electrode sets to control the applied voltage level as a function of the temperature level. The electrode wires in each electrode set can be electrically isolated from the other electrode wires and controlled separately to provide improved control of the energy delivery to the vehicle.

[0018] In yet another aspect of the invention, a plurality of electrode assemblies are provided in a kit. Each of the assemblies in the kit includes first and second electrode sets which are offset an axial distance along a shaft and in which the electrode sets are radially extendible to a radial distance. The axial distance and radial distance of each electrode assembly in the kit is selected for a selected tumor size, thereby providing a series of electrode assemblies suitable for use in ablating tumors of various sizes, thereby providing a series of electrode assemblies suitable for use in ablating tumors of various sizes. Preferably, the axial distance is less than four times the radial distance.

[0019] The foregoing and other objects and advantages of the invention will appear from the following description. In this description, reference is made to the accompanying drawings, which form a part hereof, and in which there is shown by way of illustration, a preferred embodiment of the invention. Such embodiment and its particular objects and advantages do not define the scope of the invention, however, and reference must be made therefore to the claims for interpreting the scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] Fig. 1 is a perspective view of two umbrella electrode assemblies providing first and second electrode wires deployed per the present invention at opposite edges of a tumor to create a lesion encompassing the tumor by a passing current between the electrodes;

[0021] Fig. 2 is a schematic representation of the electrodes of Fig. 1 as connected to a voltage controlled oscillator and showing temperature sensors on the electrode wires for feedback control of oscillator voltage;

[0022] Fig. 3 is a fragmentary cross-sectional view of a tip of a combined electrode assembly providing for the first and second electrode wires of Fig. 1 extending from a unitary shaft arranging the wires of the first and second electrodes in concentric tubes and showing an insulation of the entire outer surface of the tubes and of the tips of the electrode wires;

[0023] Fig. 4 is a simplified elevational cross-section of a tumor showing the first and second electrode positions and comparing the lesion volume obtained from two electrodes operating per the present invention, compared to the lesion volume obtained from two electrodes operating in a monopolar fashion;

[0024] Fig. 5 is a figure similar to that of Fig. 2 showing electrical connection of the electrodes of Fig. 1 or Fig. 3 to effect a more complex control strategy employing temperature sensing from each of the first and second electrodes and showing the use of a third skin contact plate held in voltage between the two electrodes so as to provide independent current control for each of the two electrodes;

[0025] Fig. 6 is a graph plotting resistivity in ohms-centimeters vs. frequency in Hz for tumorous and normal liver tissue, showing their separation in resistivity for frequencies below approximately 100 kHz;

[0026] Fig. 7 is a figure similar to that of Figs 2 and 5 showing yet another embodiment in which wires of each of the first and second electrodes are electrically isolated so that independent voltages or currents or phases of either can be applied to each wire to precisely tailor the current flow between that wire and the other electrodes; and

[0027] Fig. 8 is a flow chart of a program as may be executed by the controller of Fig. 7 in utilizing its multi-electrode control.

DETAILED DESCRIPTION OF THE INVENTION

[0028] Referring now to Fig. 1, a liver 10 may include a tumor 12 about which a lesion 14 will be created by the present invention using two umbrella-type electrode assemblies 16a

and 16b having a slight modification as will be disclosed below. Each electrode assembly 16a and 16b has a thin tubular metallic shaft 18a and 18b sized to be inserted percutaneously into the liver 10. The shafts 18a and 18b terminate, respectively, at shaft tips 20a and 20b from which project trifurcated electrodes 22a and 22b are formed of wires 32. The wires 32 are extended by means of a plunger 24 remaining outside the body once the shafts 18a and 18b are properly located within the liver 10 and when extended, project by an extension radius separated by substantially equal angles around the shaft tips 20a and 20b. The exposed ends of the wires 32 are preformed into arcuate form so that when they are extended from the shafts 18a and 18b they naturally splay outward in a radial fashion.

[0029] Umbrella electrode assemblies 16a and 16b of this type are well known in the art, but may be modified, in one embodiment of the invention, by providing electrical insulation to all outer surfaces of the shafts 18a and 18b, in contrast to prior art umbrella electrode assemblies which leave the shaft tips 20a and 20b uninsulated, and by insulating the tips of the exposed portions of the wires 32. The purpose and effect of these modifications will be described further below.

[0030] Per the present invention, the first electrode 22a is positioned at one edge of the tumor 12 and the other electrode 22b positioned opposite the first electrode 22a across the tumor 12 center. The term "edge" as used herein refers generally to locations near the periphery of the tumor 12 and is not intended to be limited to positions either in or out of the tumor 12, whose boundaries in practice, may be irregular and not well known. Of significance to the invention is that a part of the tumor 12 is contained between the electrodes 22a and 22b.

[0031] Referring now to Figs. 1 and 2, electrode 22a may be attached to a voltage controlled power oscillator 28 of a type well known in the art providing a settable frequency of alternating current power whose voltage amplitude (or current output) is controlled by an external signal. The return of the power oscillator 28 is connected to electrodes 22b also designated as a ground reference. When energized, power oscillator 28 induces a voltage between electrodes 22a and 22b causing current flow therebetween.

[0032] Referring now to Fig. 4, prior art operation of each electrode 22a and 22b being referenced to a skin contact plate (not shown) would be expected to produce lesions 14a and 14b, respectively, per the prior art. By connecting the electrodes as shown in Fig. 2, however, with current flow therebetween, a substantially larger lesion 14c is created. Lesion 14c also has improved symmetry along the axis of separation of the electrodes 22a and 22b. Generally, it has been found preferable that the electrodes 22a and 22b are separated by 2.5 to 3 cm for typical umbrella electrodes or by less than four times their extension radius.

[0033] Referring again to Fig. 2, temperature sensors 30, such as thermocouples, resistive or solid-state-type detectors, may be positioned at the distal ends of each of the exposed wires 32 of the tripartite electrodes 22a and 22b. For this purpose, the wires 32 may be small tubes holding small conductors and the temperature sensors 30 as described above. Commercially available umbrella-type electrode assemblies 16a and 16b currently include such sensors and wires connecting each sensor to a connector (not shown) in the plunger 24.

[0034] In a first embodiment, the temperature sensors 30 in electrode 22a are connected to a maximum determining circuit 34 selecting for output that signal, of the three temperature sensors 30 of electrode 22, that has the maximum value. The maximum determining circuit 34 may be discrete circuitry, such as may provide precision rectifiers joined to pass only the largest signal, or may be implemented in software by first converting the signals from the temperature sensors 30 to digital values and determining the maximum by means of an executed program on a microcontroller or the like.

[0035] The maximum value of temperature from the temperature sensors 30 is passed by a comparator 36 (which also may be implemented in discrete circuitry or in software) which compares the maximum temperature to a predetermined desired temperature signal 38 such as may come from a potentiometer or the like. The desired temperature signal is typically set just below the point at which tissue boiling, vaporization or charring will occur.

[0036] The output from the comparator 36 may be amplified and filtered according to well known control techniques to provide an amplitude input 39 to the power oscillator 28. Thus it will be understood that the current between 22a and 22b will be limited to a point where the temperature at any one temperature sensors 30 approaches the predetermined desired temperature signal 38.

[0037] While the power oscillator 28 as described provides voltage amplitude control, it will be understood that current amplitude control may instead also be used. Accordingly, henceforth the terms voltage and current control as used herein should be considered interchangeable, being related by the impedance of the tissue between the electrodes 22b and 22a.

[0038] In an alternative embodiment, current flowing between the electrodes 22a and 22b, measured as it flows from the power oscillator 28 through a current sensor 29, may be used as part of the feedback loop to limit current from the power oscillator 28 with or without the temperature control described above.

[0039] In yet a further embodiment, not shown, the temperature sensors 30 of electrode 22b may also be provided to the maximum determining circuit 34 for more complete temperature

monitoring. Other control methodologies may also be adopted including those provided for weighted averages of temperature readings or those anticipating temperature readings based on their trends according to techniques known to those of ordinary skill in the art.

[0040] Referring now to Fig. 3, the difficulty of positioning two separate electrode assemblies 16a and 16b per Fig. 1 may be reduced through the use of a unitary electrode 40 having a center tubular shaft 18c holding within its lumen, the wires 32 of first electrode 22a and a second concentric tubular shaft 42 positioned about shaft 18c and holding between its walls and shaft 18c wires 44 of the second electrode 22b. Wires 44 may be tempered and formed into a shape similar to that of wires 32 described above. Shaft 18c and 42 are typically metallic and thus are coated with insulating coatings 45 and 46, respectively, to ensure that any current flow is between the exposed wires 32 rather than the shafts 18c and 42.

[0041] As mentioned above, this insulating coating 46 is also applied to the tips of the shafts 18a and 18b of the electrode assemblies 16a and 16b of Fig. 1 to likewise ensure that current does not concentrate in a short circuit between the shafts 18a and 18b but in fact flows from the wires 32 of the wires of electrodes 22a and 22b.

[0042] Other similar shaft configurations for a unitary electrode 40 may be obtained including those having side-by-side shafts 18a and 18b attached by welding or the like.

[0043] Kits of unitary electrode 40 each having different separations between first electrode 22a and second electrode 22b may be offered suitable for different tumor sizes and different tissue types.

[0044] As mentioned briefly above, in either of the embodiments of Figs. 1 and 3 the wires 32 may include insulating coating 46 on their distal ends removed from shafts 18c and 42 so as to reduce high current densities associated with the ends of the wires 32.

[0045] In a preferred embodiment, the wires of the first and second electrodes 22a and 22b are angularly staggered (unlike as shown in Fig. 2) so that an axial view of the electrode assembly reveals equally spaced non-overlapping wires 32. Such a configuration is also desired in the embodiment of Fig. 2, although harder to maintain with two electrode assemblies 16a and 16b.

[0046] The frequency of the power oscillator 28 may be preferentially set to a value much below the 450 kHz value used in the prior art. Referring to Fig. 6, at less than 100 kHz and being most pronounced and frequencies below 10 kHz, the impedance of normal tissue increases to significantly greater than the impedance of tumor tissue. This difference in impedance is believed to be the result of differences in interstitial material between tumor and

regular cell tissues although the present inventors do not wish to be bound by a particular theory. In any case, it is currently believed that the lower impedance of the tumorous tissue may be exploited to preferentially deposit energy in that tissue by setting the frequency of the power oscillator 28 at values near 10 kHz. Nevertheless, this frequency setting is not required in all embodiments of the present invention.

[0047] Importantly, although such frequencies may excite nerve tissue, such as the heart, such excitation is limited by the present bi-polar design.

[0048] Referring now to Fig. 5, the local environment of the electrodes 22a and 22b may differ by the presence of a blood vessel or the like in the vicinity of one electrode such as substantially reduces the heating of the lesion 14 in that area. Accordingly, it may be desired to increase the current density around one electrode 22a and 22b without changing the current density around the other electrode 22a and 22b. This may be accomplished by use of a skin contact plate 50 of a type used in the prior art yet employed in a different manner in the present invention. As used herein, the term contact plate 50 may refer generally to any large area conductor intended but not necessarily limited to contact over a broad area at the patient's skin.

[0049] In the embodiment of Fig. 5, the contact plate 50 may be referenced through a variable resistance 52 to either of the output of power oscillator 28 or ground per switch 53 depending on the temperature of the electrodes 22a and 22b. Generally, switch 53 will connect the free end of variable resistance 52 to the output of the power oscillator 28 when the temperature sensors 30 indicate a higher temperature on electrode 22b than electrode 22a. Conversely, switch 53 will connect the free end of variable resistance 52 to ground when the temperature sensors 30 indicate a lower temperature on electrode 22b than electrode 22a. The comparison of the temperatures of the electrodes 22a and 22b may be done via maximum determining circuits 34a and 34b, similar to that described above with respect to Fig. 2. The switch 53 may be a comparator driven solid-state switch of a type well known in the art.

[0050] The output of the maximum determining circuits 34a and 34b each connected respectively to the temperature sensors 30 of electrodes 22a and 22b may also be used to control the setting of the potentiometer 52. When the switch 53 connects the resistance 52 to the output of the power oscillator 28, the maximum determining circuits 34a and 34b serve to reduce the resistance of resistance 52 as electrode 22b gets relatively hotter. Conversely, when the switch 53 connects the resistance 52 to ground, the maximum determining circuits 34a and 34b serve to reduce the resistance of resistance 52 as electrode 22a gets relatively

hotter. The action of the switch 53 and switch 52 is thus generally to try to equalize the temperature of the electrodes 22a and 22b.

[0051] If electrode 22a is close to a heat sink such as a blood vessel when electrode 22b is not, the temperature sensors 30 of electrode 22a will register a smaller value and thus the output of maximum determining circuit 34a will be lower than the output of maximum determining circuit 34b.

[0052] The resistance 52 may be implemented as a solid state devices according to techniques known in the art where the relative values of the outputs of maximum determining circuits 34a and 34b control the bias and hence resistance of a solid state device or a duty cycle modulation of a switching element or a current controlled voltage source providing the equalization described above.

[0053] Referring now to Fig. 7, these principles may be applied to a system in which each wire 32 of electrodes 22a and 22b is electrically isolated within the electrode assemblies 16a and 16b and driven by separate feeds 53 through variable resistances 54 connected either to the power oscillator 28 or its return. Electrically isolated means in this context that there is not a conductive path between the electrodes 22a and 22b except through tissue prior to connection to the power supply or control electronics. As noted before, a phase difference can also be employed between separate feeds 53 to further control the path of current flow between electrode wires 32. This phase difference could be created, e.g. by complex resistances that create a phase shift or by specialized waveform generators operating according to a computer program to produce an arbitrary switching pattern. The values of the resistances 54 are changed as will be described by a program operating on a controller 56. For this purpose, the variable resistances 54 may be implemented using solid-state devices such as MOSFET according to techniques known in the art.

[0054] Likewise, similar variable resistances 54 also controlled by a controller 56 may drive the contact plate 50.

[0055] For the purpose of control, the controller 56 may receive the inputs from the temperature sensors 30 (described above) of each wire 32 as lines 58. This separate control of the voltages on the wires 32 allows additional control of current flows throughout the tumor 12 to be responsive to heat sinking blood vessels or the like near any one wire.

[0056] Referring to Fig. 8, one possible control algorithm scans the temperature sensors 30 as shown by process block 60. For each temperature sensor 30, if the temperature at that wire 32 is above a “ceiling value” below a tissue charring point, then the voltage at that wire is

reduced. This “hammering down” process is repeated until all temperatures of all wires are below the ceiling value.

[0057] Next at process block 62, the average temperature of the wires on each electrode 22a and 22b is determined and the voltage of the contact plate 50 is adjusted to incrementally equalize these average values. The voltage of the contact plate 50 is moved toward the voltage of the electrode 22 having the higher average.

[0058] Next at process block 64 the hammering down process of process block 60 is repeated to ensure that no wire has risen above its ceiling value.

[0059] Next at process block 66 one wire in sequence at each occurrence of process block 66 is examined and if its temperature is below a “floor value” below the ceiling value but sufficiently high to provide the desired power to the tumor, the voltage at that wire 32 is moved incrementally away from the voltage of the wires of the other electrode 22. Conversely, if the wire 32 is above the floor value, no action is taken.

[0060] Incrementally, each wire 32 will have its temperature adjusted to be within the floor and ceiling range by separate voltage control.

[0061] As shown in Fig. 7, this process may be extended to an arbitrary number of electrodes 22 including a third electrode set 22c whose connections are not shown for clarity.

[0062] While this present invention has been described with respect to umbrella probes, it will be understood that most of its principles can be exploited using standard needle probes energized in a bipolar configuration. Further it will be understood that the present invention is not limited to two electrode sets, but may be used with multiple electrode sets where current flow is predominantly between sets of the electrodes. The number of wires of the umbrella electrodes is likewise not limited to three and commercially available probes suitable for use with the present invention include a 10 wire version. Further although the maximum temperatures of the electrodes were used for control in the above-described examples, it will be understood that the invention is equally amenable to control strategies that use average temperature or that also evaluate minimum temperatures.

[0063] It is specifically intended that the present invention not be limited to the embodiments and illustrations contained herein, but modified forms of those embodiments including portions of the embodiments and combinations of elements of different embodiments as come within the scope of the following claims.